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09/500,977	02/15/2000	James W. Soong		5482

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James W. Soong
521 Susana Avenue
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EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/500,977

Applicant(s)

SOONG, JAMES W.

Examiner

Carolyn M Bleck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23,24,27,28 and 30-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,23,24,27,28 and 30-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 4 February 2004.
Claims 21, 23-24, 27-28, and 30-44. Claims 21, 22, and 38 have been amended.
Claims 22, 25-26, and 29 have been cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21, 23-24, 27-28, 30-32, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (6,516,315) in view of Wilkins (6,523,009) and Schoenberg et al. (6,322,502) for substantially the same reasons given in the previous Office Action (paper number 9).

(A) As per claims 21 and 24, Gupta discloses a method for controlling access to information used in a health care application in a client/ server architecture over a network (Abstract; col. 8 line 60 to col. 9 line 9, col. 12 lines 12-25) comprising:

(a) managing data objects at multiple levels in a database management system used in a healthcare information system comprising medical directors, attendings,

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PCPs, specialists, and residents (reads on "healthcare organization"), wherein at the finest level, the object may be a single attribute value in a particular instance, wherein a patient folder associated with a specific patient consists of objects having subjects such as patient bio-data, insurance, financial, problems, encounters, and treatment records (Fig. 4, col. 3 lines 35-59, col. 8 line 60 to col. 9 line 9, col. 11 line 35 to col. 12 line 25); ("data objects, wherein the object may be a single attribute value in a particular instance" are considered to be a form of Applicant's "component fields");

(b) defining a set of access rights initiated when a subject/user tries to perform an operation on a data object by both physicians or a patient's primary care provider (reads on "health care providers") and patients (reads on "non health care providers"), the access rules defined by an "administrator" (col. 4 line 1 to col. 5 line 15, col. 6 lines 5-43, col. 7 line 45 to col. 8 line 33, col. 9 lines 10-68);

(c/d) granting a user, such as a primary care provider, access to certain defined (reads on "predetermined") data objects based on a set of access rights, wherein an example of Gupta's method is as follows (see Figure 1, col. 3 lines 35-59): "A subject, Dr. Smith has a relationship with an object entitled John Doe's patient folder. By virtue of this relationship, Dr. Smith has a potential to access to the patient folder of John Doe. However, Dr. Smith does not have indiscriminate access to all parts of the folder. The relationship between the subject and the object specifies the role of the subject for the object. The role in this case is that of a Primary Care Provider (PCP). The patient folder is marked with security classification labels that indicate the type of information from a security perspective and its sensitivity. Every role is defined with access rights

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that preferably include security classification labels and function classifications. Thus, Dr. Smith has read-only access to the part of the folder that is marked as PatientBio, except the part that is marked PatientBioSensitive. He also has read-only access to the part of the folder that is marked as PatientFinancial, except the part that is marked PatientFinancialSensitive. He has full access to the parts of the folder marked PatientClinical, including the parts that are marked PatientClinicalSensitive.”

(Figure 1 and 4-5, col. 7 line 45 to col. 8 line 32, col. 11 lines 60-68) (It is noted that Gupta's "role defined with access rights that preferably include security classification labels and function classifications" are considered to be a form of "first access parameter is present");

(e) granting access to certain data objects based on a set of access rights, wherein granting access as discussed above in sections c/d includes granting access to subjects based on specific roles, wherein the subjects include the CFO having access to PatientFinancial and PatientFinancial Sensitive information and the Consultant having access to PatientClinical and PatientBio information, wherein the subjects CFO and Consultant gain access to different types of data objects, and wherein the PCP discussed above in section c/d has access to PatientBio, PatientFinancial, and PatientClinicalSensitive (Figure 1 and 4-5, col. 7 line 45 to col. 8 line 32, col. 11 lines 60-68) (It is noted that the CFO, Consultant, and PCP have access to different data objects within Gupta's system based on a role defined with access rights that preferably include security classification labels and function classifications); and

(f) denying a user access to a data object if no relationship exists between the user and the data object (Figures 4-5, col. 7 line 45 to col. 8 line 63, col. 11 lines 35-68, col. 12 lines 25-30) (It is noted that in Figure 5, if no relationship exists between the user and the user's role and the data object, the user is denied access to the data object).

Gupta is entirely silent as to the person who determines access rules. Gupta discloses only that an administrator defines the rules (col. 4 line 1 to col. 5 line 15, col. 6 lines 5-43, col. 7 line 45 to col. 8 line 33, col. 9 lines 10-68).

Wilkins includes a patient owned and controlled electronic medical record, wherein the patient determines who has access the electronic medical record (Abstract; col. 2 lines 9-33, col. 5 line 65 to col. 6 line 58).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include Wilkins's feature of allowing a patient to determine access within Gupta's method with the motivation of protecting the privacy of patient information (Wilkins; col. 1 lines 65-67), providing a patient reasonable quick and easy access to patient information (Wilkins; col. 2 lines 9-15), and providing a patient access to review insurance information exchanged between a health care provider and insurer (Wilkins; col. 2 lines 25-33).

Gupta fails to expressly disclose "a first predetermined group of the component fields relating to a first medical condition of the patient" and "a second predetermined group of the component fields relating to a second medical condition of the patient."

Schoenberg discloses selecting subsets of a patient information, wherein when the job function is "doctor", the subsets include patient history, physical examination

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data, current drug data, problem data, orders, progress notes, and summary reports, and wherein when the job function is "nurse", the subsets include problem data, care plan, orders, and critical pathways. The Examiner respectfully submits that the "doctor" subsets of data and "nurse" subsets of data are considered to be a form of "a first medical condition" and "second medical condition".

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Schoenberg within the method taught collectively by Gupta and Wilkins with the motivation of precisely controlling access to a patient's information (Gupta; col. 1 lines 19-25).

(B) Claims 23-24, 27-28, 30-32, and 39-44 have not been amended and are rejected for the same reasons given in the prior Office Action (paper number 4; section 3(A)-3(M); pages 2-10).

(C) Claim 38 repeats the same limitations as claim 21, and is therefore rejected for the same reasons given for claim 21, and incorporated herein.

4. Claims 33-34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. (6,024,699) for substantially the same reasons given in the previous Office Action (paper number 9). Further reasons appear below.

(A) As per claim 33-34, Surwit discloses a method for a medical data processing system (col. 1 lines 5-11) comprising:

(a) providing a server connected to one or devices or monitors, wherein the server includes database for storing and manipulating patient data (col. 9 lines 24-48);

(b) identifying emergency medical conditions within the server based on physiological data, behavioral data, and patient name data, collected (Figure 8, col. 12 line 15 to col. 16 line 57 and col. 17 lines 1-15);

(c) analyzing data transmitted from a patient monitoring system substantially simultaneously with the transmission thereof to the server to identify emergency medical conditions requiring immediate medical attention (col. 23 lines 20-25); and

(d) automatically communicating treatment information to the respective patient monitoring system (reads on "non healthcare provider") for the patient for an identified emergency medical condition (col. 23 lines 25-30).

It is respectfully submitted that Surwit's "identifying emergency medical conditions within the server based on physiological or behavioral data collected" (col. 12 line 15 to col. 16 line 57 and col. 17 lines 1-15) is considered to be a form of a threshold event as the patient's medical condition is above a certain level. It would be an obvious modification to include using a specific threshold event within the method of Surwit with the motivation of immediately notifying medical personnel of an emergency (Surwit; col. 2 lines 55-63).

As per the recitation of "the threshold event defined by the patient", it is respectfully submitted that typically in patient monitoring, a patient would agree with a medical professional as to what events or conditions of a patient are to be monitored, and therefore it would have been an obvious modification to the method of Surwit to

include allowing a patient to define a threshold event with the motivation of facilitating patient behavior modification (Surwit; col. 4 lines 28-38).

As per the recitation of to a non health care provider "selected by the patient", it is respectfully submitted that Surwit's system provides for automatic communication of information, and typically in health care management, a patient must provide approval for communicating medical information to an outside approval. Therefore, it would have been an obvious modification to the method of Surwit to include a non health care provider "selected by the patient" with the motivation of ensuring the privacy of a patient's medical information is protected.

(B) Claim 37 have not been amended and are rejected for the same reasons given in the prior Office Action (paper number 4; section 4(A)-4(B); pages 10-12).

5. Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. (6,024,699) as applied to claim 33 above, and further in view of Campbell et al. (6,208,974), for substantially the same reasons given in the previous Office Action (paper number 9). Further reasons appear below.

(A) Claims 35-36 have not been amended and are rejected for the same reasons given in the prior Office Action (paper number 4; section 5(A); pages 12-13).

Response to Arguments

6. Applicant's arguments filed 4 February 2004 have been fully considered but they are not persuasive. Applicant's arguments will be addressed in the order in which they appear in the response filed 4 February 2004.

(A) At pages 9-13 of the 4 February 2004 response, Applicant argues that the features of the invention in claims 21 and 38 are not taught by the applied references.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 4 February 2004 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Gupta, Wilkins, and/or Shoenberg, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (paper number 9), and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of

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the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(B) At page 11 of the response filed 4 February 2004, Applicant argues that nothing teaches or motivates the combination of the cited patents except improper hindsight.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Further, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. However, although the Examiner agrees that the motivation or suggestion to make modifications must be articulated, it is respectfully contended that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves.

References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).

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(C) At page 11 of the response filed 4 February 2004, Applicant argues that the applied patents teach away from the claimed invention.

In response, the Examiner is unable to find anything in the Gupta reference that precludes or "teaches away from" an ability to allow the administrator of the Gupta method to be a patient. Furthermore, Gupta was not relied upon for teaching "patient participation". Wilkins was clearly relied upon in the rejection above for teaching access to data by a patient.

Furthermore, the Examiner submits that the Gupta reference does not teach away from the applied combination of references or the Applicant's invention. Gupta suggests several advantages that the invention is intended to provide for users, including the ability to precisely controlling access to a patient's information (Gupta; col. 1 lines 19-25).

Moreover, when considering and applying prior art to claim limitations, alternate embodiments may be considered. According to MPEP §2123, "a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments." *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) Gupta discloses that "it should be understood that the foregoing is illustrative and not limiting and the obvious modifications may be made by those skilled in the art..." The Examiner interprets this phrasing to mean the aspects disclosed and summarized in the passage are parts of a

limited or preferred embodiment that does not preclude other possible embodiments that have alternate configurations that still provide the disclosed advantages of the Gupta method (Gupta; col. 1 lines 19-25).

(D) At pages 12-13 of the response filed 4 February 2004, Applicant argues that even if Gupta and Wilkins are able to be combined, their combined teachings do not produce my claimed invention.

In response, the Examiner respectfully disagrees. In the Examiner's rejection of claim 21 above, it was clearly shown that Gupta taught the following:

(a) managing data objects at multiple levels in a database management system used in a healthcare information system comprising medical directors, attendings, PCPs, specialists, and residents (reads on "healthcare organization"), wherein at the finest level, the object may be a single attribute value in a particular instance, wherein a patient folder associated with a specific patient consists of objects having subjects such as patient bio-data, insurance, financial, problems, encounters, and treatment records (Fig. 4, col. 3 lines 35-59, col. 8 line 60 to col. 9 line 9, col. 11 line 35 to col. 12 line 25); ("data objects, wherein the object may be a single attribute value in a particular instance" are considered to be a form of Applicant's "component fields"); and

(b) defining a set of access rights initiated when a subject/user tries to perform an operation on a data object by both physicians or a patient's primary care provider (reads on "health care providers") and patients (reads on "non health care providers"), the

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access rules defined by an "administrator" (col. 4 line 1 to col. 5 line 15, col. 6 lines 5-43, col. 7 line 45 to col. 8 line 33, col. 9 lines 10-68).

Furthermore, the Examiner admits that Gupta is entirely silent as to the person who determines access rules. Gupta discloses only that an administrator defines the rules (col. 4 line 1 to col. 5 line 15, col. 6 lines 5-43, col. 7 line 45 to col. 8 line 33, col. 9 lines 10-68). Therefore, the Examiner relied upon Wilkins for teaching a patient owned and controlled electronic medical record, wherein the patient determines who has access the electronic medical record (Abstract; col. 2 lines 9-33, col. 5 line 65 to col. 6 line 58).

Thus, it is the position of the Examiner that the combination of references, namely Gupta, Wilkins, and/or Shoenberg teaches Applicant's invention, and thus the rejection is maintained.

In response to Applicant's statements regarding claim 27, the Examiner respectfully submits that a patient could be a "personal relation who is not a medical care provider of the patient".

(E) At pages 13-14 of the response filed 4 February 2004, Applicant argues that the applied references do not teach the limitations of claims 33-37.

In response, the Examiner respectfully notes that neither of the Surwit or Campbell references were ever applied as references under 35 U.S.C. 102 against the pending claims. As such, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches the claimed features, *per se*, but

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rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of these features.

Regarding this issue, it is well established that references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

- (i) obviousness does not require absolute predictability;
- (ii) non-preferred embodiments of prior art must also be considered; and
- (iii) the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate

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obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In this case, each limitation recited in claims 33-37 has been addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Surwit and Campbell based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as clearly detailed in the remarks and explanations given above, and incorporated herein.

As such, it is respectfully submitted that Applicant appears to view the applied references in a vacuum without considering the knowledge of average skill in the art.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches medical record management system and process with improved workflow features (5,974,389) and health monitoring and diagnostic device and network-based health assessment and medical records maintenance system (6,602,469).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306 or (703) 872-9326 [Official communications]

(703) 872-9327 [After Final communications labeled "Box AF"]


(703) 746-8374 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB

CB

March 22, 2004


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600

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